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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,095	11/22/2000	Aaron I. Vinik	05216.00001	5818

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	14

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/717,095	Vinik et al.
Examiner	**Art Unit**
Hope Robinson	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 26, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's response to the Office Action mailed November 26, 2001 in Paper No. 10 on February 26, 2002 is acknowledged.

2. Claims 1, 5, 8, 15, 16 and 18 have been amended. Claims 1-24 are pending.

3. Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,840,531, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP 1404, 1442.01 and 1442.04.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-24 are rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses that the present invention is directed to a preparation of a mammalian protein or polypeptide portions thereof involved in islet cell neogenesis and to provide a DNA molecule encoding a mammalian protein involved in islet cell neogenesis. However, the specification does not clearly set forth how the polypeptide is involved in islet cell neogenesis. Further, the claims recite an isolated DNA molecule encoding a mammalian islet cell neogenesis associated protein (INGAP) and the specific sequence with no limitation to the function of the polypeptide (see claims 1, 12 and 17). In addition, the application only describes an INGAP set forth in SEQ ID NOs: 1 and 2 (DNA and the encoding protein), therefore, the specification fails to describe representative species. Moreover, the claims are directed to portions of the claimed protein (see for example claims 17 and 24), therefore, the claims are drawn to a large variable genus of polypeptides for which the activity has not been described or recited in the claims. Note also that claim 19 is directed to a fragment of the nucleotide sequence and the specification does disclose if these nucleotides encode the claimed protein. Thus, the specification fails to describe other representative species from other sources or by identifying characteristics or structural properties other than being an islet neogenesis associated protein (i.e, plays a role in stimulation of islet neogenesis without adequately describing the role). Further, there is no indication in the

specification or the claim regarding the amount of variation among species within the genus, structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure and no common structural attributes are given that would allow one skilled in the art to identify members of the genus. One skilled in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and it also fails to give adequate written description.

Therefore, for all these reasons, the specification is not considered to be enabling without undue experimentation, because, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable one skilled in the art to be able to practice the invention commensurate in scope with these claims.

5. The response file February 26, 2002 in Paper No. 10 is not convincing regarding the rejection under 35 U.S.C. 112, first paragraph, thus, the rejection remains. It is noted that applicant cited *In re Gosteli* however, this argument is not convincing. Applicant's response on pages 2-5 state that the written description guidelines doesn't require that applicant teach how the claimed nucleotide sequence exert a physiological effect. This statement is not persuasive as "portions/fragments" of the sequence is claimed and there's no indicia from the claim or specification that the same function is achieved with the fragments/portions of the sequence. If the invention is not adequately described then it doesn't demonstrate possession. Applicant also contends that the function of the encoded protein is not required, which is incorrect as fragments

of the protein is claimed and the function of the protein is necessary. It is stated also that because the claimed genus of DNA molecules is limited to those that encode a particular recited amino acid sequence, the genus does not require disclosure of a large number of species. Applicant is directed to Example 13 of the Written Description Guidelines, which provides a discussion on protein variants which the claims encompass. The response also states that the claims are directed to polynucleotides not polypeptides. This statement is limited because a limitation to the claim is that the DNA encodes a particular protein and fragments of the protein. It is asserted that "the function of the DNA is not limited to the protein coding capacity as the function depends on DNA hybridization. Any of the claimed portions would thus be useful irrespective of the activity of the encoded polypeptides". This assertion is not persuasive as any DNA could hybridize to the claimed sequence, however, may not encode the claimed protein with the asserted function. Therefore, a functional limitation is necessary in the claim. Therefore, the rejection of record is maintained.

6. Claims 17 and 24 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent.

The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application. Note that claims 17 with the recitation of "all or a portion of a protein shown in SEQ ID NO: 2" is improper recapture for broadening. Claim 75 in 08/709,662 which corresponds to claim 17 in the present application was amended to put the claims in condition for allowance by inserting the phrase "wherein the gene encodes a protein as shown in SEQ ID NO: 2". Whereas, the present application now amends the same claim to recite "which encodes all or a portion of a protein as shown in SEQ ID No: 2". This attempt to broaden the claims which was rejected in an office action in the parent file above in the re-issue application is a clear example of recapture, which is prohibited. In addition, claim 24 which also recites the language "portion of" also inappropriately broadens the claim.

7. Applicant's response on pages 5-7 states that claim 17 of the present application has an enlarged scope which is prohibited in reissues filed within two years of a patent's grant. The response also contends that claim 75 of the parent file was amended to over come an enablement rejection which alleged that the originally filed claim was overly broad for reciting " any nucleic acid encoding any INGAP from any source. Thus, the amendment limited the claim to a specific mammalian INGAP nucleotide sequence. Therefore, the rejection should be withdrawn".

However, applicants assertions are not completely accurate, as the office action in the parent file (08/709,662) stated that applicant is only enabled for the specific nucleic acid disclosed in the specification that encode specific polypeptides, thus, applicant was not enabled for fragments of the claimed sequence. In view of the foregoing the rejection remains.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 11 and 14 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite because it is not clear what "detectable moiety" the claim is referring to (see also claim 14).

9. Applicant's response states that the specification clearly teaches the meaning of detectable moieties. However, the limitations of the specification cannot be read into the claims, thus, this argument is not convincing and the rejection remains.

The Basis For Non-Statutory Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-24 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No. 09/659,379. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are directed to a recombinant construct for expression of INGAP which comprises a nucleotide sequence that

encodes the amino acids set forth in SEQ ID NO: 6. Note that the present application is directed to an isolated DNA molecule which encodes an INGAP protein set forth in SEQ ID NO: 2 and both sequences are identical with the exception of one residue (SEQ ID NO: 6 has an additional Methionine in the beginning of the sequence). Furthermore, the present application and copending application both claim probes, primers and have claims directed to antisense strands which would render each other obvious. Although the claims in the two applications are not identical the claimed subject matter in both applications are an obvious variation of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Regarding the rejection under 35 U.S.C. 103, Double Patenting, applicant's response on pages 9-11 state that the two applications were not filed simultaneously and that the Patent Office controlled the rate of prosecution of the applications leading to the instant application. Applicant also contends that a two-way obviousness determination should be reciprocal and concludes that the two applications are not obvious variations of each other. Applicant is reminded that in the process of reissue, rejections that were not previously made can be applied, therefore, the contention that Patent Office controlled the rate of prosecution of the applications is not persuasive, especially since applicant also states that filing of the two applications was not simultaneous. Further, that type of argument has no bearing on the rejection of record. In addition, the filing date does not have any bearing on the finding of obviousness type double

patenting, if the double patenting rejection is the only issue remaining then one application is allowed and the other would require the filing of a terminal disclaimer as stated in the MPEP. The double patenting rejection as applied above remains relevant for the reasons stated above and because applicant did not provide any arguments that addressed the substance of the rejection. The two applications although differ in scope are obvious variations of each other with regard to the claimed DNA encoding proteins that are substantially homologous and claims to probes, primers etc., as stated in the previous office action. Thus, this ground of rejection has been maintained.

Conclusion

13. No claims are allowable.

14. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no

event,however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday- Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS

Patent Examiner

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